

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 2

		<i>Complete if Known</i>	
Application Number	09/510,560		
Filing Date	February 22, 2000		
First Named Inventor	Kenneth I. Cumming		
Art Unit	1639		
Examiner Name	Jeffrey S. Lundgren		
Attorney Docket Number	9701-6		

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No.	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code (if known)			
1.	5,190,748		03-02-1993	Bachynsky et al.	
2.	6,326,360 B1		12-04-2001	Kanazawa et al.	
3.	2007/0292512 A1		12-20-2007	Leonard et al.	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No.	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Country Code, Number, Kind Code (if known)				
4.	EP 0370481 A2		11-21-1989	F. Hoffmann-La Roche AG		
5.	EP 0376534 A1		07-04-1990	Riker Laboratories, Inc.		
6.	EP 0580074 A1		01-26-1994	ASTA Medica Aktiengesellschaft and Eisai Co., Ltd.		
7.	JP 2202027		11-19-1990	Riker Laboratories, Inc.		
8.	JP 0040645		02-19-1994	Eisai Co., Ltd.		
9.	JP 11083458		02-09-1999	Teikoku Seiyaku KK		
10.	JP 2004329953		09-30-2004			
11.	WO 93/05903 A1		04-01-1993	Hadley Industries PLC		
12.	WO 93/21907		11-11-1993	Leiras Oy		
13.	WO 99/02120 A2		01-21-1999	D-Pharm Ltd.		
14.	WO 99/02485 A1		01-21-1999	D-Pharm Ltd.		
15.	WO 99/45934 A1		09-16-1999	Grelan Pharmaceutical Co.		
16.	WO 00/22909 A2		04-27-2000	Biotech Australia PTY. Limited		
17.	WO 02/092070		11-21-2002	Elan Corporation, PLC		
18.	WO 03/047493 A2		06-12-2003	DOR BIOPHARMA INC.		

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T
	19.	AUNGST, "Structure/effect studies of fatty acid isomers as skin penetration enhancers and skin irritants," Pharm. Res. 6:244-247 (1989)	
	20.	CHAN et al., "Depsipeptide (FR901228, NSC-630176) pharmacokinetics in the rat by LC/MS/MS," Invest. New Drugs 15:195-206 (1997).	
	21.	MISHIMA et al., "Studies on the Promoting Effects of Medium Chain Fatty Acid Salts on the Nasal Absorption of Insulin in Rats," J. Pharmacobio-Dyn., 10:624-631 (1987).	
	22.	MORISHITA et al., "Site-Dependent Effect of Aprotinin, Sodium Caprate, Na <sub>2</sub> EDTA and Sodium Glycocholate on Intestinal Absorption of Insulin," Biol. Pharm. Bull. 16:68-72 (1993).	
	23.	SCHNEIDER et al., "Evaluation of drug penetration into human skin ex vivo using branched fatty acids and propylene glycol," Int. J. Pharm. 145:187-196 (1996)	
	24.	YAMAMOTO et al., "Pulmonary absorption enhancement of peptides by absorption enhancers and protease inhibitors," J. Control. Release, 41:57-67 (1996).	

Examiner Signature	Date Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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25.	YANG et al., Deposition of insulin powders for inhalation in vitro and pharmacodynamic evaluation of absorption promoters in rats," Acta Pharmaceutica Sinica 40:1069-1074 (2005).	
26.	ZHOU et al., "Effects of cholic acid and other enhancers on the bioavailability of insulin from a subcutaneous site," Int. J. Pharm. 69:29-41 (1991).	
27.	Application No. 11/450,641; Filed: 06/09/2006; Office Action Mailed 6/25/2009	

Examiner Signature	/Jeffrey Lundgren/	Date Considered	<b>11/5/2009</b>
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